

510(k) SUMMARY

JUN 17 2009

SALINE WOUND WASH

1. Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Premier Brands of America Inc.
120 Pearl St.
Mount Vernon, NY 10550

Telephone No.: (718) 325-3000
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Contact Person: Mack Cauthen
mcauthen@premier-brands.com

Date Prepared: May 26, 2009

2. Name of Device and Name/Address of Sponsor

Premier Saline Wound Wash

Premier Brands of America Inc.
120 Pearl St.
Mount Vernon, NY 10550

3. Name of Device

Proprietary: Premier Sterile Saline Wound Cleanser
Classification Name: Lavage, Jet (21 CFR 880.5475)
Product Code: FQH

4. Classification of Device: 2

5. Description

Saline Wound Wash is a multi-use, isotonic, sterile saline solution packaged in a bag-in-can aerosol system. Actuation of the device (product can) delivers a consistent flow of sterile isotonic saline solution at published safe and effective wound impact pressures of 4 to 15 psi (Clinical Practice Guideline Number 15, AHCPR, US Department of Health and Human Services). The mechanical action of isotonic saline solution moving across the wound aids in the removal of foreign material, such as dirt and debris, as well as any necrotic tissue, wound exudates, and other extraneous matter. No preservatives are added since the finished device

is sterilized by gamma irradiation under parameters that have been validated according to ISO/AAMI 11137 requirements (Sterilization of health care products – Requirements for validation and routine control – radiation sterilization).

Saline Wound Wash passes the USP<71> Sterility Test.

Saline Wound Wash is an Rx and OTC device and will only be labeled for use in wounds.

6. Predicate Device

OTC: Wound Wash Saline; Blairex Laboratories, Inc. (K083355)

RX: Dermacyn™ Wound Dressing (K041161)
Sterile Saline (K082330)

7. Intended Use/Indication for Use

Indications for Rx (Prescription) Use:

Saline Wound Wash is intended for use by or under the direction of a professional health care provider in moistening and lubricating absorbent wound dressings, cleansing and maintaining a moist wound environment for traumatic wounds such as pressure sores, leg ulcers of diabetic and vascular origin, cuts abrasions and minor burns.

Indications for Over the Counter (OTC) Use:

Saline Wound Wash is intended for use in moistening and lubricating absorbent wound dressings and for cleansing minor wounds, scrapes and minor burns. If redness, swelling or bleeding continues please seek the help of a nurse, nurses aid, doctor or other medical professional.

8. Technological Characteristics

Saline Wound Wash is an aerosol bag-in-can system. The propellant, compressed air, is charged into the container between bag and the can creating a means to dispense the contents of the bag, isotonic sterile saline solution. The bag is a 4-Layer laminate system including a sandwiched polyethylene layer establishing an impermeable barrier between the propellant (compressed air) and the bag contents (sterile isotonic saline). The isotonic saline solution is in contact with either a polyethylene or polypropylene layer. Saline Wound Wash is a clear, colorless 0.9% sodium chloride solution prepared from sodium Chloride, USP, and purified water, USP. After filling and pressurizing, the device is sterilized by gamma irradiation. The product is tested against established specifications and meets USP sterility requirements.

9. Substantial Equivalence

Saline Wound Wash is as safe and effective as the predicate devices. Saline Wound Wash has the same intended uses, technological characteristics, and basic principles of operation as its predicate devices and raises no new issues of safety or effectiveness. Thus Saline Wound Wash is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 17 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Premier Brands of America, Incorporated
% Mr. Mack Cauthen
Manager, Quality and Regulatory Affairs
120 Pearl Street
Mount Vernon, New York 10550

Re: K090848

Trade/Device Name: Saline Wound Wash
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet Lavage
Regulatory Class: II
Product Code: FQH, FRO
Dated: May 26, 2009
Received: June 3, 2009

Dear Mr. Cauthen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing

Page 2-Mr. Mack Cauthen

practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090848

Device Name: Saline Wound Wash

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)


(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)
and Restorative Devices